

**REMARKS**

Claims 30, 31, 34, 38-46, 48, 49, 53-61 and 63-79 are pending in the application. Claims 30, 39, 45, 48-49, 67, 71, and 73-74 have been amended herein. Claims 80-81 are new. Support for the amendments to the claims and new claims can be found at least at paragraphs [0023], [0033], [0035], [0040], [0042], [0043], [0045], [0026], [0031] and [0036] of the specification as published.

**Rejections under 35 U.S.C. 103(a)**

Claims 30, 34, 38, 45, 46, 48, 49, 64 and 65 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1) for reasons of record.

Claims 31, 53, 60, 63 and 66 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Claims 61 and 67-79 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1) as applied to claims 31, 53, 60, 63 and 66 above, and further in view of Masini et al (U.S. Patent Application Publication 2001/0043918 A1).

All of the rejections of record rely on the teachings of Weiss et al. as the primary reference. The Examiner states that Weiss et al. “a polymer scaffold including at least one membrane, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface of varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns.” The Examiner further states that “Weiss et al teaches

that the scaffold is made of a polymer, but Weiss et al does not explicitly teach that the polymer is a synthetic biopolymer.” The Examiner relies on Kale as allegedly teaching a “polymer scaffold made of a synthetic biopolymer.” The Examiner relies on Mancini et al. as allegedly teaching “a polymer scaffold having a membrane which may be a mesh.” The Examiner concludes that the substitution of the “polymer scaffold made of a synthetic biopolymer” of Kale and/or the “polymer scaffold having a membrane which may be a mesh” of Mancini into the scaffolds of Weiss et al. render all of the presently-pending claims obvious. Applicants traverse.

Applicants respectfully submit that the scaffolds of Weiss et al. are quite distinguishable from those of the claimed invention in ways much more significant than the choice of polymer. Quite clearly, Weiss et al. is directed to a tissue engineering technique that requires mechanical fastening of layers of polymer to form higher-ordered structures. Weiss et al. teaches barbs, pins, screws, sutures, and the like in the mechanical assembly of the disclosed structures. In one instance, it is mentioned that “[b]arbs can be about 25 to 250 microns in height, depending on the dimensions of the scaffold’s porous microstructure.” The Examiner equates the fasteners, *e.g.*, barbs, of Weiss et al. with the “features” of the membranes of the claimed invention. The Examiner states that there is no patentable weight given to the process limitations in Applicant’s. Applicants submit this constitutes is an improper reading of the claims.

First, the fasteners of Weiss et al. are extraneous to the layers being attached by said fasteners. The fasteners, *e.g.*, barbs, screws, sutures, are not comprised in the layers of Weiss et al., rather they are attached mechanically to said layers. Applicant’s invention, by contrast, is directed to biopolymeric membranes microfabricated to include structural features as having defined dimensions. The structural features are an integral part of the membranes, formed by the molding processes used to fabricate the membranes, *i.e.*, the features are generated in the membranes, from the membrane biopolymer material, based on the architecture of the selected

elastomeric mold. Nothing in Weis et al. teaches such a membranes having these defined integral features and nothing in Kale et al or Mancini et al. rectifies this deficiency of teaching.

In order to advance prosecution, Applicants have again amended the claims to recite inventive features of Applicant's scaffolds. In particular, independent claims 31 and 67 have been amended to incorporate limitations previously presented in dependent claims 65 and 79 and to further define the architecture of the biopolymer membranes featured in the claimed scaffolds. Applicants respectfully submits that Weiss et al (in combination with the secondary references of record) fails to suggest the invention as presently claimed. Applicants request reconsideration and withdrawal of the rejection.

### **CONCLUSION**

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. MITY-001CNRCE2.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

Electronic signature: /Debra J. Milasincic, Esq./  
Debra J. Milasincic, Esq.  
Registration No.: 46,931  
NELSON MULLINS RILEY &  
SCARBOROUGH LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(800) 237-2000(617) 742-4214 (Fax)  
Attorney/Agent For Applicant